K132456

510(k) SUMMARY

SUBMITTED BY: BECTON, DICKINSON AND COMPANY
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NOV 0 7 2013

DATE PREPARED: October 23, 2013

DEVICE TRADE NAME: BD Veritor™ System for Rapid Detection of RSV

DEVICE COMMON NAME: Antigens Cf (including Cf Controls) Respiratory Syncytial Virus

DEVICE CLASSIFICATION: 21 CFR § 866.3480

PREDICATE DEVICE: Quidel QuickVue RSV 10 test

INTENDED USE:

The BD Veritor™ System for Rapid Detection of Respiratory Syncytial Virus (RSV) is a chromatographic immunoassay with an instrumented read for the direct and qualitative detection of RSV fusion protein from a direct nasopharyngeal swab from patients suspected of having a viral respiratory infection. This test is intended for in vitro diagnostic use to aid in the diagnosis of RSV infections in infants and pediatric patients under the age of 6 years. Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or for other management decisions. A negative test is presumptive. It is recommended that negative test results be confirmed by viral cell culture or an alternative method, such as a FDA-cleared molecular assay. The test is intended for professional and laboratory use. It is to be used in conjunction with the BD Veritor™ System Reader.

DEVICE DESCRIPTION:

The BD RSV test is a chromatographic assay to qualitatively detect RSV fusion protein in samples processed from respiratory specimens. The processed specimen is added to the test device where RSV viral antigen binds to anti-RSV antibodies conjugated to detector particles on the RSV test strip. The antigen-conjugate complex migrates across the test strip to the reaction area and is captured by an antibody line on the membrane. Results are interpreted by the BD Veritor™ System Reader, a portable electronic device which uses a reflectance-based measurement method to evaluate the line signal intensities on the assay test strip, and applies specific algorithms to determine the presence or absence of any target analyte(s). A liquid crystal display (LCD) on the instrument communicates the results to the operator.

DEVICE COMPARISON:

The BD Veritor™ System for Rapid Detection of RSV was compared to the Quidel QuickVue RSV 10 test (**k101918**)

Product Feature	BD Veritor™ System for RSV	Quidel QuickView RSV 10 test (k101918)
Intended Use	The BD Veritor™ System for Rapid Detection of Respiratory Syncytial Virus (RSV) is a chromatographic immunoassay with an instrumented read for the direct and qualitative detection of RSV fusion protein from a direct nasopharyngeal swab from patients suspected of having a viral respiratory infection. This test is intended for in vitro diagnostic use to aid in the diagnosis of RSV infections in infants and pediatric patients under the age of 6 years. Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or for other management decisions. A negative test is presumptive. It is recommended that negative test results be confirmed by viral cell culture or an alternative method, such as a FDA-cleared molecular assay. The test is intended for professional and laboratory use. It is to be used in conjunction with the BD Veritor™ System Reader.	The QuickVue RSV 10 test is an immunoassay that allows for the rapid, qualitative detection of respiratory syncytial virus (RSV) antigen directly from nasopharyngeal swab 'and nasopharyngeal aspirate/wash specimens for symptomatic pediatric patients (less than six years old). The test is intended for use as an aid in the rapid diagnosis of acute RSV infection. Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or for other management decisions. A negative test is presumptive. It is recommended that negative test results be confirmed by cell culture. The test is intended for professional and laboratory use.
Specimen Types	Nasopharyngeal swab	Nasopharyngeal swab
Assay Technology	Immunochromatographic	Immunochromatographic
Detection Format	An opto-electronic reader determines the line intensity at each of the spatially-defined test and control line positions, interprets the results using the scoring algorithm, and reports a positive, negative, or invalid result on the LCD screen based on pre-set thresholds.	Visual determination of presence or absence of pink-to-red Test Line and the appearance of a blue Procedural Control Line on the test strip indicate the presence of RSV antigen.
Qualitative	Yes	Yes
Total Assay Time	10 minutes	10 minutes
Control format	• Kit RSV positive and RSV negative dry swab external controls • Internal positive control • Internal negative control	• Kit RSV positive control swab • Kit RSV negative control swab • Internal control lines

SUMMARY OF PERFORMANCE DATA:

Analytical Sensitivity

The limit of detection (LOD) for the BD Veritor System for Rapid Detection of RSV test was established for the following RSV strains. The LOD for each strain represents the lowest concentration producing a positivity rate of ≥95% based on testing 60 or more replicates.

Viral Strain	Calculated LOD ($TCID_{50}$/mL)	No. Positive / Total	% Positive
VR-26 (Long Subgroup A)	$1.43X10^5$	57/60	95.0
VR-955 (9320 subgroup B)	$3.98X10^4$	57/60	95.0
VR-1540 (A-2)	$1.94X10^3$	59/60	98.3
VR-1580 (Washington subgroup B)	$1.08X10^4$	58/60	96.7
VR-1400 (Wild Type subgroup B)	$2.96X10^3$	76/80	95.0

$TCID_{50}$/mL = 50% Tissue Culture Infectious Dose

Analytical Specificity (Cross Reactivity)

The **BD Veritor** System for Rapid Detection of RSV test was evaluated with bacteria and yeast at a target concentration of approximately 5 x 10^6 CFU/mL (CFU – Colony Forming Units). The viruses were evaluated at concentrations of 10^5TCID_{50}/mL or greater. Of the microorganisms tested, none showed cross-reactivity in the RSV test.

Bacteriodes fragilis	*Neisseria* sp.*(Neisseria perflaus)*
Bordetella pertussis	*Neisseria subflava*
Candida albicans	*Peptostreptococcus anaerobius*
Chlamydia pneumoniae	*Porphyromonas asaccharolyticus*
Corynebacterium diphtherium	*Prevotella oralis*
Escherichia coli	*Propionibacterium acnes*
Fusobacterium nucleatum	*Proteus mirabilis*
Haemophilus influenzae	*Pseudomonas aeruginosa*
Haemophilus parainfluenzae	*Serratia marcescens*
Kingella kingae	*Staphylococcus aureus*
Klebsiella pneumoniae	*Staphylococcus epidermidis*
Lactobacillus sp.	*Streptococcus mutans*
Legionella sp.	*Streptococcus pneumoniae*
Moraxella catarrhalis	*Streptococcus pyogenes*
Mycobacterium tuberculosis	*Streptococcus* sp. Group C
Mycoplasma pneumoniae	*Streptococcus* sp. Group G

Neisseria gonorrhoeae	*Streptococcus salivarius*
Neisseria meningitidis	*Veillonella parvula*
Neisseria mucosa	

Adenovirus, Type 1
Adenovirus, Type 7
Cytomegalovirus
Enterovirus
HSV Type 1
Human coronavirus OC43
Human metapneumovirus (hMPV-27 A2)
Human Parainfluenza
Influenza A/California/7/2009 H1N1
Influenza A/Brisbane/10/2007 H3N2
Influenza A/Victoria/3/75 H3N2
Influenza B/Brisbane/60/2008
Influenza B/Florida/4/2006
Influenza B/Lee/40
Measles virus
Mumps virus
Rhinovirus

Interfering Substances

Various substances were evaluated with the **BD Veritor** System for Rapid Detection of RSV test. These substances included whole blood (2%) and various medications. No interference was noted with this assay for any of the substances at the concentrations tested.

Substance	Concentration
Whole Blood	2%
4-Acetamidophenol	10 mg/mL
Acetylsalicylic acid	20 mg/mL
Chlorpheniramine maleate	5 mg/mL
Dextromethorphan	10 mg/mL
Diphenhydramine HCl	5 mg/mL
Guaiacol Glyceryl Ether	20 mg/mL
Ibuprofen	10 mg/mL
Loratidine	100 ng/mL
Menthol Throat Lozenges	10 mg/mL
Ayr Saline Nasal Gel	10 mg/mL
Oxymetazoline	0.05 mg/mL
Phenylephrine	1 mg/mL
Pseudoephedrine HCl	20 mg/mL

Substance	Concentration
Synagis	4 □g/mL
Amantadine Hydrochloride	500 ng/mL
Beclomethasone	500 ng/mL
Budesonide	500 ng/mL
Dexamethasone	10 mg/mL
Fexofenadine	500 ng/mL
FluMist	1%
Flunisolide	500 ng/mL
Fluticasone	500 ng/mL
Mometasone	500 ng/mL
Mupirocin	500 ng/mL
Oseltamivir	500 ng/mL
Purified Mucin Protein	1 mg/mL
Ribavirin	500 ng/mL

Two OTC mouthwashes	5 %
Four OTC nasal sprays	10 %
Four OTC throat drops	12.5 %
Homeopathic Allergy Medicine	10 mg/mL
Albuterol	0.083 mg/mL

Rimantadine	500 ng/mL
Tobramycin	500 ng/mL
Triamcinolone	500 ng/mL
Zanamivir	1 mg/mL

CLINICAL STUDIES

Performance characteristics for the BD Veritor System for Rapid Detection of RSV test were established in a prospective multi-center clinical study conducted at eight POC U.S. testing sites during the 2012-2013 respiratory season. The performance of the BD Veritor RSV test was compared to a commercially available PCR method as well as viral culture. A total of 540 specimens were enrolled in the clinical trial. A total of 523 specimens had evaluable results for all three testing methods: PCR, viral cell culture and BD Veritor RSV. The study population was 42.6 % females and 57.4% males. The table below shows age distribution of the study population.

Demographics Summary – Age Group		
Age Group	**Number**	**Percentage**
<2	305	58.3
2 - 5	218	41.7
Total	***523***	***100***

The table below summarizes the performance obtained with clinical specimens using the BD Veritor™ System RSV test in comparison to a commercially available PCR. The overall positive percent agreement (PPA) and negative percent agreement (NPA) of the BD Veritor™ System RSV with a PCR comparator, based on these 523 specimens, are 81.6% (146/179) and 99.1% (341/344), respectively.

BD Veritor™ RSV Compared to PCR			
	PCR		
BD Veritor RSV	**P**	**N**	
P	146	3	*149*
N	33	341	*374*
	179	*344*	*523*
Reference Method: PCR PPA: 81.6% (95% C.I: 75.2%, 86.6%) NPA: 99.1% (95% C.I: 97.5%, 99.7%)			

BD Veritor™ System RSV test performance compared to viral cell culture was also evaluated in this study. For the same 523 specimens 91.8% (123/134) were positive by both BD Veritor RSV and cultures, 93.3% (363/389) were negative by both BD Veritor RSV and culture. There were 26 BD Veritor RSV positive, viral cell culture negative specimens of which 23 were demonstrated to be RSV positive by an FDA cleared molecular assay.

Invalid rates for the BD Veritor™ System for Rapid Detection of RSV were calculated by dividing the number of invalids by the total number of evaluable specimens tested by the Veritor System. The overall invalid rate for the BD Veritor™ System for RSV based on the 523 specimens was determined to be 0.2% (1/523, 95% CI: 0.03%, 1.07%).

Reproducibility

The reproducibility of the BD Veritor System for Rapid Detection of RSV test was evaluated at three clinical laboratory sites. The reproducibility panel was composed of 12 simulated RSV samples. These included moderate positive samples, low positive samples (near the assay limit of detection), and high negative samples (i.e., containing very low concentrations of virus) and negative samples. The panel was tested by two operators at each site for five consecutive days. The results are summarized below.

BD Veritor™ RSV Reproducibility (% RSV Positive Results)				
Sample	**P1**	**P2**	**S1**	**Total**
High negative RSV	6.7% (2/30) (1.8%, 21.3%)	6.7% (2/30) (1.8%, 21.3%)	13.3% (4/30) (5.3%, 29.7%)	8.9% (8/90) (4.6%, 16.6%)
Low positive RSV	90.0% (27/30) (74.4%, 96.5%)	76.7% (23/30) (59.1%,88.2%)	80.0% (24/30) (62.7%, 90.5%)	82.2% (74/90) (73.1%, 88.8%)
Moderate positive RSV	100% (30/30) (88.6%, 100%)	100% (30/30) (88.6%, 100%)	100% (30/30) (88.6%, 100%)	100% (90/90) (95.9%, 100%)
Negative	0% (0/30) (0%, 11.3%)	0% (0/30) (0%, 11.3%)	0% (0/30) (0%, 11.3%)	0% (0/90) (0%, 4.1%)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

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DIRECTOR, QUALITY SYSTEM AND REGULATORY AFFAIRS
BECTON, DICKINSON AND COMPANY, BD DIAGNOSTICS
10865 ROAD TO THE CURE, SUITE 200
SAN DIEGO CA 92121

November 7, 2013

Re: K132456
Trade/Device Name: BD Veritor™ System for Rapid Detection of RSV
Regulation Number: 21 CFR 866.3480
Regulation Name: Respiratory syncytial virus serological reagents
Regulatory Class: I
Product Code: GQG
Dated: July 31, 2013
Received: August 14, 2013

Dear Mr. Payne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Sally A Hojvat -S

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
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Enclosure

510(k) Number: K132456

Device Name: BD Veritor™ System for Rapid Detection of RSV

Indications for Use:

The **BD Veritor™** System for Rapid Detection of Respiratory Syncytial Virus (RSV) is a chromatographic immunoassay with an instrumented read for the direct and qualitative detection of RSV fusion protein from a direct nasopharyngeal swab from patients suspected of having a viral respiratory infection. This test is intended for *in vitro* diagnostic use to aid in the diagnosis of RSV infections in infants and pediatric patients under the age of 6 years. Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or for other management decisions. A negative test is presumptive. It is recommended that negative test results be confirmed by viral cell culture or an alternative method, such as a FDA-cleared molecular assay. The test is intended for professional and laboratory use. It is to be used in conjunction with the BD Veritor™ System Reader.

Prescription Use √ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

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